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13 UNITED STATES DISTRICT COURT

14 DISTRICT OF ARIZONA

15 In Re Bard IVC Filters Products  
16 Liability Litigation

No. MD-15-02641-PHX-DGC

17 **PLAINTIFFS' RESPONSE TO  
18 DEFENDANTS C. R. BARD, INC.'S  
19 AND BARD PERIPHERAL  
20 VASCULAR, INC.'S MOTION TO  
21 EXCLUDE THE OPINIONS OF  
22 ROBERT O. RITCHIE, PH.D.**

23 Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Robert O.  
24 Ritchie, Ph.D. ("Motion" or "Mot.") [Doc. 7316]. Plaintiffs incorporate in this response  
25 their Omnibus Statement of Law and Generally-Applicable Arguments in opposition to  
26 Bard's Motion to Exclude Plaintiffs' Experts and Rule 702 and *Daubert* ("Omnibus  
27 Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth below  
28 and in the Omnibus Memorandum, this Court should deny the Motion.

29 **I. INTRODUCTION**

30 Dr. Ritchie is a mechanical engineer with special expertise in materials science.  
31 He was retained by Plaintiffs to examine several Bard IVC filters that had failed in order  
32 to provide an opinion as to why the failures occurred. He concluded that the filter devices  
33 were defectively designed and manufactured and unsafe for implant in the human body.  
34 Notably, Defendants do not challenge these opinions.

1       Instead, Defendants seek to exclude four opinions expressed by Dr. Ritchie that lie  
 2 on the periphery of his proffered testimony. The four opinions collectively represent only  
 3 a small fraction of the analysis Dr. Ritchie set forth in his reports and deposition  
 4 testimony. None of the opinions targeted by Defendants relate to the core of his  
 5 testimony: namely, that the Bard filters he examined failed for reasons that have been well  
 6 documented in the literature regarding Bard's filters. Nonetheless, each of the opinions  
 7 challenged by Defendants is based on a scientifically sound methodology and will assist  
 8 the trier of fact. For this reason, Defendants' motion should be denied.

9 **II. ARGUMENT**

10       Consistent with Case Management Order No. 26 [Doc. 6799], and in the interest of  
 11 judicial economy, Plaintiffs incorporate by reference Plaintiffs' Omnibus Statement of  
 12 Law in Opposition to Bard's Motions to Exclude Plaintiffs' Experts Under Rule 702 and  
 13 *Daubert* [Doc. 7799]. Plaintiffs rely specifically on sections I, II(B), and II(D) of their  
 14 omnibus brief.

15       **A. Dr. Ritchie's background in mechanical engineering and materials  
 16 science qualifies him to opine on Bard's IVC filters.**

17       Dr. Ritchie is currently the H.T. & Jessie Chua Distinguished Professor of  
 18 Engineering, Professor in the Department of Materials Science & Engineering, and  
 19 Professor of Mechanical Engineering at the University of California, Berkeley. Mot. Ex.  
 20 A, Ritchie March 2, 2017 Report, at 106. He is also Senior Faculty Scientist in the  
 21 Materials Sciences Division of the Lawrence Berkeley National Laboratory, and an  
 22 affiliated member of the UCSF/UC Berkeley Bioengineering group. *Id.* He was  
 23 Chairman of the UC Berkeley Materials Science & Engineering Department from 2005 to  
 24 2011. *Id.*

25       Dr. Ritchie received a Ph.D. in Materials Science in 1973 from Cambridge  
 26 University. *Id.* His career in academia has taken him from Cambridge to M.I.T. to the  
 27 University of California at Berkeley. *Id.* He has served as a consultant for both  
 28 government and industry, including in the medical field on behalf of Abbott Vascular,

1 ATS Medical, Baxter, Cordis, Carbomedics, Edwards, Guidant, CV Medical, Medstone,  
2 NDC, Shiley, Sorin, and St. Jude Medical. *Id.* Dr. Ritchie is well known for his research  
3 in the fields of materials science, fracture mechanics and particularly fatigue, having  
4 authored or co-authored over 700 papers and authored or co-authored over 700 papers and  
5 edited 19 books in the technical literature (he is one of ISI's Highly Cited Authors in  
6 Materials Science). *Id.* During the course of his career Dr. Ritchie has received numerous  
7 awards, is a member of the National Academy of Engineering, and is a Fellow of the  
8 Materials Research Society, the American Society for Materials, and the American  
9 Society for Mechanical Engineers. *Id.* at 106-107.

10 Over the past forty-five years Dr. Ritchie has performed extensive research into the  
11 problem of fracture and fatigue of metallic alloys. Mot. Ex. C, Ritchie May 12, 2017,  
12 Rebuttal Report at 1. He has significant experience in the analysis of failures in medical  
13 devices specifically. *Id.* He has testified on numerous occasions before the Food and  
14 Drug Administration on issues pertaining to the fatigue, fracture and endurance of medical  
15 devices. *Id.* While Dr. Ritchie has not published on IVC filters, he has voluminous  
16 knowledge of the fatigue and failure of Nitinol (the alloy from which Bard filters are  
17 made) based on thirty years of active research on this material. *Id.*

18       **B. Dr. Ritchie is qualified to rely on published literature and the analysis  
19 of other experts to opine on failure rates.**

20 Bard maintains Dr. Ritchie is not qualified to opine on IVC failure rates because he  
21 is not a biostatistician or epidemiologist. This argument is a red herring – neither  
22 Plaintiffs nor Dr. Ritchie ever claimed that he was qualified to analyze raw adverse event  
23 data in order calculate failure rates. Rather, and as discussed *infra*, Dr. Ritchie relied on  
24 two distinct sources of information for his opinion regarding high failure rates: (1) the  
25 rates reported in the published literature; and (2) the relative risks that were calculated by  
26 Plaintiffs' expert Dr. Betensky, who is indisputably qualified to make these calculations.  
27 Thus, Dr. Ritchie did not attempt to calculate a failure rate, but instead relied on  
28

1 calculations performed by others and then opined on the significance of those calculated  
 2 rates. This was reasonable, and customary for experts.

3 Defendants never explain why a mechanical engineer with more than four decades of  
 4 experience researching and testing failures in medical devices is not qualified to render an  
 5 opinion on whether a given failure rate can be characterized as “high” or “unacceptable.”  
 6 Such opinions are part and parcel of the conclusions that any materials scientist would  
 7 render when evaluating the performance of a device.

8 In addition to questioning Dr. Ritchie’s qualifications, Defendants also argue that  
 9 Dr. Ritchie’s methodology was flawed because he couldn’t identify the rate of failure or  
 10 the sources he relied upon. Mot. at 6. This argument is particularly bewildering given  
 11 that, in the very same section that Defendants make this argument, they quote at length  
 12 from the portion of Dr. Ritchie’s deposition where *he identifies a reported failure rate as*  
 13 *well as a number of sources that he is relying on for his opinions*. In the testimony quoted  
 14 by Defendants, Dr. Ritchie testified that he reviewed one study that demonstrated a failure  
 15 rate of forty percent. Mot. Ex. A, Ritchie Dep. Tr., at 133:5-12. In this same section of  
 16 his testimony, Dr. Ritchie referenced at least two sources by name that he is relying on for  
 17 his opinions regarding failures rates: the Nicholson study and the expert report of  
 18 Dr. Betensky. *Id.* at 133:5-134:5.

19 These sources were also identified and discussed in Dr. Ritchie’s expert report, in  
 20 addition to many others. Mot. Ex. B, Ritchie March 2, 2017, Report, at 3-4. Thus, while  
 21 Dr. Ritchie did not recite line and verse from each of the studies he is relying on during  
 22 his deposition, his expert report clearly identifies the studies. *Id.* (citing reference  
 23 numbers 6-11). Many of these studies utilize the same terminology as Dr. Ritchie when  
 24 describing the observed failure rates. *See, e.g.*, Ex. A, Kalva et al., *Recovery’ vena cava*  
 25 *filter: Experience in 96 patients*, Cardiovasc. Intervent. Radiol. 2006, 29:559-64, at 563  
 26 (“We found a high incidence of asymmetric deployment of the filter legs, fractures of the  
 27 device, and asymptomatic caval penetration by the filter arms.”); Ex. B, Hull et al., *Bard*  
 28 *Recovery filter: Evaluation and management of vena cava limb perforation, fracture and*

1      *migration*, J. Vasc. Interv. Radiol. 2009, 20: 52-60, at 57 (“the Recovery filter is  
 2      associated with a high rate of IVC arm perforation and structural weakness”).

3      Dr. Ritchie’s opinions regarding the high rate of complications in Bard’s filters  
 4      simply echo what is already reported in the literature. For this reason, his opinions should  
 5      not be excluded because they bear the hallmark of a scientifically reliable methodology.  
 6      *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) (key indicia of reliability  
 7      is whether the expert’s methods are employed outside the courtroom).

8      In addition to the peer-reviewed literature, Dr. Ritchie also relied on the analysis of  
 9      Dr. Betensky for his opinions that the extent of complications in Bard filters is  
 10     unacceptable. Dr. Betensky is a biostatistician who was retained by Plaintiffs to conduct a  
 11     statistical analysis of adverse event reports for Bard’s retrievable filters as compared to  
 12     the 1995 Simon Nitinol Filter (“SNF”). Dr. Ritchie utilized the reporting risk ratios that  
 13     Dr. Betensky calculated in order to assess the comparative performance of Bard IVC  
 14     filters. Although Defendants suggest that such reliance is improper, courts routinely  
 15     admit testimony of experts who rely on other experts with regard to matters outside their  
 16     field of expertise. *See, e.g., Apple Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1321 (Fed. Cir.  
 17     2014), *overruled on other grounds by Williamson v. Citrix Online, LLC*, 792 F.3d 1339,  
 18     1349 (Fed. Cir. 2015) (en banc) (“Experts routinely rely upon other experts hired by the  
 19     party they represent for expertise outside of their field”); *Dura Automotive Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 609; 13 (7th Cir. 2002) (“[I]t is common in technical  
 20     fields for an expert to base an opinion in part on what a different expert believes on the  
 21     basis of expert knowledge not possessed by the first expert.”); *Calva-Cerqueira v. United States*, 281 F.Supp.2d 279, 300 (D.D.C. 2003) (“an expert economist may rely on the  
 22     opinions of other experts”). So long as this Court determines that Dr. Betensky’s opinions  
 23     satisfy the requirements of *Daubert*, there is no reason Dr. Ritchie may not rely on them.

24      In the end, Defendants are left to assert that an expert who specializes in materials  
 25     science should be forbidden from observing that failure rates as high as 40% are  
 26     unacceptable. Yet not even Bard would dispute that a 40 percent failure rate in an

1 implanted medical device is unacceptably high, and therefore Dr. Ritchie's testimony  
 2 should not be excluded.

3       **C. Dr. Ritchie's description of the "vicious circle" is based on a reliable  
 4 methodology.**

5           Defendants next target Dr. Ritchie's opinion that one complication can increases  
 6 the risk of other complications, leading to a "vicious circle" of multiple complications.  
 7 Defendants' suggest this opinion is mere conjecture and is not based on any data.  
 8 However, Bard's own witnesses have already agreed with Dr. Ritchie that filter  
 9 complications can work synergistically, such that the presence of one complication (e.g.  
 10 tilting) can increase the risk of other complications (e.g. migration). Moreover, there is  
 11 data from both Dr. McMeeking and published literature to support Dr. Ritchie's opinions  
 12 regarding the interconnected nature of filter complications.

13           Dr. Ritchie succinctly explained his reference to a vicious cycle during his  
 14 deposition:

15           Q. Now let's talk about tilt as it relates to perforation for a moment. What do  
 16 you rely on to opine that tilt can lead to perforation?

17           A. Well, again, it's—there's a series—McMeeking has done calculations on  
 18 this and has certain theories, but my feeling on this has been that – that  
 19 there's a linkage with some—with migration as well. Some degree of tilt  
 20 means that you have an anchor that's not anchored, and that means that the  
 21 ability of the filter to move is obviously elevated because you're not fully  
 22 anchored. Once the filter starts to move, the probability of perforation is  
 23 likely, and all these things relate to the possibility of fracture and—'cause  
 24 that's what we talked about earlier with the crack growing in different  
 25 directions. So I've—I've always seen this as what I call a vicious circle. It's  
 26 a synergy of events.

27           Ex. C, Ritchie Dep. Tr., at 123:5-21. The potential for a synergistic relationship among  
 28 different types of complications lies at the heart of Dr. Ritchie's concept of a vicious  
 circle. In Dr. Ritchie's report, he provides an illustration of this phenomenon whereby a  
 facture of one leg leads to tilting which then results in migration and could ultimately lead  
 to perforation. Mot. Ex. B at 36.

1       A former Bard vice-president confirms that Bard was well aware of the synergism  
 2 among different types of complications. Christopher A. Ganser was the head of quality  
 3 assurance at Bard during the period from 2003 to 2007. Ex. D, Ganser Dep. T., at 14:12-  
 4 15:14. He testified that he knew that tilting could increase the risk of other complications:

5       Q. When you were involved with -- I'm going to talk about the  
 6 recovery in the G2 filter right now. You knew that there were  
 7 issues with both of those devices not staying perfectly centered in  
 8 the vena cava, true?

9       A. I knew there were reports of complaints where there was tilting.

10      Q. And that tilting was a condition that could put a patient at an  
 11 increased risk of perforations, of migrations, of fracture and of  
 12 the device not working for its intended purpose of stopping  
 13 pulmonary embolisms. Did you know that?

14      A. The tilting could contribute to that.

15      Id. at 71:5-18.

16      The published literature also supports Dr. Ritchie's opinions, at least with respect  
 17 to the relationship between tiling and migration. In a study published in 2009, the authors  
 18 determined there was a statistically significant relationship between a tilt of more than 15  
 19 degrees and subsequent migration. Ex. E, Binkert et al., *Technical Success and Safety of*  
*Retrieval of the G2 Filter in a Prospective, Multicenter Study*, Journal of vascular and  
 20 interventional radiology, 20 (2009), 1449-53, at 1452. Thus, Dr. Ritchie's description of a  
 21 vicious circle is consistent with actual data and is not, as Defendants suggest, some  
 22 untested hypothesis.

23      Finally, the expert report of Dr. McMeeking repeatedly echoes Dr. Ritchie's  
 24 assessment regarding the synergistic relationship between filter complications. For  
 25 example, Dr. McMeeking writes:

26      In addition, fracture, through removing legs or arms or both, will  
 27 make the remaining body of the filter more prone to tilt as it will be  
 28 asymmetric, and the loss of legs, and arms in some cases, will make  
 migration of the remaining body of the filter more probable as it will  
 be less firmly attached to the vena cava wall. It is also possible that  
 the asymmetry of the remaining filter body after fracture will lead to  
 force distributions on the wall of the vena cava that will accelerate  
 the rate at which one or more of the limbs penetrates and perforates

1           the vena cava wall. This point applies to all filters considered in this  
 2 report.

3 Ex. A to Defendants' Motion to Exclude of Robert M. McMeeking [Doc. 7314],  
 4 McMeeking March 3, 2017 Report, at 25; *see also id.* at 10 ("I have found that perforation  
 5 contributes to tilting, and tilting contributes to perforation."), 12 (noting that tilt increases  
 6 probability of fracture as a result of "alternating strains [that] are increased because of the  
 7 larger span between the points where the filter limbs engage the wall of the vena cava").

8           Although Dr. McMeeking shares Dr. Ritchie's assessment regarding the  
 9 interrelationship among different complications, Defendants did not seek to exclude  
 10 Dr. McMeeking's opinion on this issue. Their decision undermines Defendants' assertion  
 11 that Dr. Ritchie's opinions regarding the "vicious circle" should be struck under *Daubert*.

12           **D.     Dr. Ritchie's decades-long experience with failure analysis renders him  
 13 qualified to opine on Bard's testing.**

14           Despite acknowledging the depth of Dr. Ritchie's experience in the field of  
 15 materials science and failure analysis, Defendants suggest that Dr. Ritchie is unqualified  
 16 to render opinions regarding the adequacy of Bard's testing. In leveling this critique,  
 17 Defendants misstate the substance of Dr. Ritchie's opinions. Dr. Ritchie did not simply  
 18 state that Bard's testing was inadequate because "some patients have experienced  
 19 complications with Bard's filters." Mot. at 12. Rather, Dr. Ritchie concluded that Bard's  
 20 testing was flawed because it failed to reveal the fractures and complications that  
 21 ultimately manifested time and time again in actual patients. Ex. C, Ritchie Dep. Tr., at  
 22 158:7-18. In this respect, Dr. Ritchie's opinion is entirely noncontroversial: it is self-  
 23 evident that *any* testing of a product should be designed to detect complications that occur  
 24 during real world use. If a testing program fails to discover a flaw that leads to an  
 25 unacceptably high failure rate in actual patients, then that program was inadequate.

26           The fact that Dr. Ritchie did not explain in precise detail how Bard's testing  
 27 protocol should have been improved is not relevant to *whether* the testing was inadequate.  
 28 Dr. Ritchie never suggested that improvements were not possible. On the contrary, he

1 identified specific steps that Bard could have been taken to improve its testing, including  
 2 (1) increasing the severity of the loading conditions, (2) increasing the duration of the  
 3 tests; (3) increasing the number of filters that were tested, and (4) testing multiple filter  
 4 sizes. Mot. Ex. B, Ritchie March 2, 2017, Report, at 28, 31.

5 Other than noting their disagreement with Dr. Ritchie's opinions, Defendants never  
 6 articulate why they find Dr. Ritchie's qualifications lacking. Nor could they. Dr. Ritchie  
 7 has been studying fatigue problems for 49 years, and has fatigue tested "virtually every  
 8 material on the planet." Mot. Ex. A, at 36:14-16. His testing experience includes setting  
 9 up protocols and working with various testing machines in the laboratory environment.  
 10 *Id.* at 37:7-18. He is "absolutely" qualified to address the adequacy of Bard's testing. *Id.*  
 11 at 37:16-18.

12       **E. Dr. Ritchie should be permitted to testify that SNF is a safer alternative  
 13 product.**

14       Defendants' final salvo is directed at Dr. Ritchie's opinion that the Simon Nitinol  
 15 Filter is a safer alternative to the Recovery, G2 and similar filters. As was the case with  
 16 Dr. Ritchie's opinion regarding high failure rates, his opinion regarding SNF is based on  
 17 the statistical analysis performed by Dr. Betensky of SNF's adverse events relative to  
 18 other Bard filters as well as studies in the published literature regarding comparative filter  
 19 complication rates. Mot. Ex. A, Ritchie Dep. Tr., at 134:10-136:6, 140:6-141:10; Mot. Ex  
 20 B, Ritchie March 2, 2017, Report, at 4.

21       The main thrust of Defendants' argument is that Dr. Ritchie may not rely on a  
 22 permanent filter (SNF) to establish a "safer alternative" to Bard's retrievable filters  
 23 because these filters are not functional equivalents. But this is a false dichotomy. As  
 24 Dr. Ritchie noted at his deposition, all of Bard's so-called retrievable filters were in fact  
 25 developed as permanent filters. Ex. C, Ritchie Dep. Tr., at 154:20-155:6. Thus, the  
 26 functional equivalence of SNF and retrievable Bard filters is a basis to include rather than  
 27 exclude SNF as a safer alternative product.

1        Defendants’ “functional equivalence” criticism was also leveled almost verbatim  
2 against Plaintiffs’ expert Dr. McMeeking in connection with Defendants’ motion to  
3 exclude Dr. McMeeking. Rather than simply rehash Plaintiffs’ response a second time,  
4 and consistent with Section I of Case Management Order No. 26, Plaintiffs incorporate by  
5 reference section III(D) of their Memorandum of Law and Arguments in Opposition to  
6 Defendants’ Motion to Exclude the Opinions of Dr. McMeeking [Doc. 7806]. As these  
7 arguments demonstrate, Bard’s suggestion of significant and dispositive functional  
8 differences between SNF and retrievable filters is contrary to Bard’s own representations  
9 and actions, the testimony of its own medical expert, and the evidence in this litigation.

10       Bard also objects to Dr. Ritchie’s testimony on the ground that he is not a medical  
11 doctor and is therefore not qualified to render an opinion on safer alternatives for a given  
12 patient. But this misconstrues the nature of Dr. Ritchie’s opinion, which is offered from  
13 an engineering and materials science perspective rather than as a medical judgment.  
14 Dr. Ritchie will not testify that for any particular patient a certain filter should have been  
15 used. Instead, he is observing that, as an engineer who specializes in failure analysis, the  
16 significant reduction in adverse event rates for SNF, combined with the known design and  
17 manufacturing defects in Bard’s retrievable filters, render SNF a safer alternative as  
18 compared to other available filters manufactured by Bard. This testimony is certainly  
19 helpful to the jury even though it is not directly applicable to the ultimate issue for a  
20 particular plaintiff, because the jury should be apprised that alternative, safer *options* were  
21 available and could have been considered.

22 **III. CONCLUSION**

23       Based on the foregoing reasons, Plaintiffs respectfully request that the Court deny  
24 Defendants’ motion to exclude Dr. Ritchie.

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1 RESPECTFULLY SUBMITTED this 27<sup>th</sup> day of September, 2017.  
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4 GALLAGHER & KENNEDY, P.A.  
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25 **CERTIFICATE OF SERVICE**  
26  
27

28 I hereby certify that on this 27<sup>th</sup> day of September, 2017, I electronically  
1 transmitted the attached document to the Clerk's Office using the CM/ECF System for  
2 filing and transmittal of a Notice of Electronic Filing.  
3  
4

5 /s/ Gay Mennuti  
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